

relieving discomfort, do not disclos nutritional supplement (as used in the above captioned patent application). Thus, SS Pharmaceutical and Tsunoda do not disclose a component identical to nutritional supplement (as used in the above captioned patent application) in orally consumable material as indicated in Applicant's claimed method.

NUTRITIONAL SUPPLEMENT AS PROVIDED IN THE METHOD CLAIMED IS A NEW (ADDITIONAL) COMPONENT NOT DISCLOSED IN THE PRIOR ART

Applicant claims a method which indicates nutritional supplement as used in the above captioned patent application. Nutritional supplement as used in the above captioned patent application, is not disclosed in SS Pharmaceutical or Tsunoda, the applied prior art for relieving discomfort. So, it is not an old composition or a use of an old composition. Rather, nutritional supplement as used in the above captioned patent application, in the unit dose as indicated in the method claimed by Applicant is a new (additional) component.

A METHOD OF USING A KNOWN COMPOSITION MAY BE PATENTABLE

Nutritional supplement as used in the above captioned patent application, in the unit dose as indicated in the method claimed by Applicant has new and nonobvious uses. These uses include being indicated by an indicator as a percent of a recommended daily amount of nutritional supplement (as used in the above captioned patent application) in the unit dose. New and nonobvious uses even of old compositions may be patentable, MPEP 2112.02 Process Claims: under Process of use Claims. The US Supreme Court approved a method of using propanil, a known composition (US patent 3,816,092), <u>Dawson Chem. Co.v Rohm & Haas Co.</u> 448 US 176, 206 USPQ 385 (1980). So, Applicant's new and nonobvious nutritional supplement (as used in the above captioned patent application), in the unit dose as indicated in the method claimed by Applicant should be patentable.

In the Advisory Action the Examiner notes that ibuprofen and vitamin C are in a dependent claim. Please note that Applicant's claims are for a method,

and not for a composition. SS Pharmaceutical and Tsunoda, the applied prior art for relieving discomfort, disclos discomfort reliever which includes vitamin(s). The vitamin(s) of SS Pharmaceutical and Tsunoda are part of the discomfort reliever, as they are adapted to aid in or contribute to discomfort relieving functions of a discomfort reliever or to aid in or contribute to reducing side effects of the discomfort reliever. SS Pharmaceutical and Tsunoda do not disclose nutritional supplement (as used in the above captioned patent application). Nutritional supplement (as used in the above captioned patent application) is in addition to vitamin(s) included in discomfort reliever, which are adapted to aid in or contribute to discomfort relieving functions of a discomfort reliever or to aid in or contribute to reducing side effects of the discomfort reliever.

PATENTABILITY IS SUPPORTED BY A NEW AND UNOBVIOUS FUNCTIONAL RELATIONSHIP BETWEEN AN ENCLOSURE AND INDICATING

SS Pharmaceutical and Tsunoda, the applied prior art for relieving discomfort, do not disclose an enclosure enclosing a unit dose and having an indicator indicating a percent of a recommended daily amount of nutritional supplement (as used in the above captioned patent application) in the unit dose. Patentability is supported by a new and unobvious functional relationship between an enclosure and indicating, Application of Miller 164USPQ 46, 49 (CCPA, 1969). Indicating may very well constitute limitations upon which patentability can be predicated, In re Royka and Martin 180 USPQ 580, 583 (CCPA, 1974). Patentability of Applicant's claims is supported by a new and unobvious functional relationship between an enclosure enclosing a unit dose of discomfort reliever and indicating a percent of a recommended daily amount of nutritional supplement (as used in the above captioned patent application) in the unit dose, Application of Miller

Thus, patentability of Applicant's claimed method is supported by providing supplements for nutrition and an indication of a percent of a recommended daily amount (or value) for each nutritional supplement. The nutritional supplements in Applicant's claimed method are in addition to any

agents in the unit dose of orally consumable mat rial, which are adapted to aid in or contribute to discomfort relieving functions of a discomfort reliever or to aid in or contribute to reducing side effects of the discomfort reliever.

ALL THE LIMITATIONS OF A CLAIM MUST BE CONSIDERED MEANINGFUL

Applicant claims a method which provides an enclosure enclosing a unit dose of discomfort reliever and nutritional supplement and indicating a percent of a recommended daily amount of nutritional supplement in the unit dose. This is not disclosed in SS Pharmaceutical and Tsunoda, the applied prior art for relieving discomfort. All of the limitations of a claim must be considered meaningful, Perkin – Elmer Corp. v Westinghouse Elec. Corp. 3 USPQ2d 1321, 1324-25 (Fed. Cir, 1987). Accordingly, the claims are patentable over SS Pharmaceutical and Tsunoda.

Each of Applicant's independent claims recites the limitations of indicating a nutritional supplement, which is not adapted to aid in or contribute to discomfort relieving functions of a discomfort reliever or to aid in or contribute to reducing side effects of the discomfort reliever. This is not disclosed in SS Pharmaceutical and Tsunoda, the applied prior art for relieving discomfort. All of the limitations of a claim must be considered meaningful, <u>Perkin – Elmer Corp.</u> Accordingly, the claims are patentable over SS Pharmaceutical and Tsunoda.

Claims 26-30, 32-35 and 37-47 have been rejected under 35 USC 103 as being unpatentable over SS Pharmaceutical in view of Tsunoda, Yeh et al and Lambelet. The Examiner notes that the instant method claims enclose agents. The agents taught to be enclosed by SS Pharmaceutical, Tsunoda, Yeh et al and Lambelet are not disclosed as providing supplements for nutrition or a percent of a recommended daily value for a nutritional supplement. Applicant claims a method which provides supplements for nutrition and an indication of a percent of a recommended daily amount (or value) for each nutritional supplement. The nutritional supplements In Applicant's claimed method are in addition to any agents in the unit dose of orally consumable material, which are adapted to aid in or contribute to discomfort relieving functions of a discomfort reliever or to aid in

or contribute to reducing side effects of the discomfort reliever. Vitamin C and B1 in SS Pharmaceutical are disclosed as part of a cold medicine and painkiller, which also contains ibuprofen, as see lines 2-3 of the abstract. Thus, vitamin C and B1 in the cold medicine and painkiller of SS Pharmaceutical are disclosed as being adapted to aid in or contribute to discomfort relieving functions of a discomfort reliever or to aid in or contribute to reducing side effects of the discomfort reliever. So, vitamin C and B1 in the cold medicine and painkiller of SS Pharmaceutical are not within the group of nutritional supplements in Applicant's claimed method.

Similarly, Vitamin C in Tsunoda is disclosed as part of a pain medicine, which also contains ibuprofen, as see first paragraph. Thus, vitamin C in the pain medicine of Tsunoda is disclosed as being adapted to aid in or contribute to discomfort relieving functions of a discomfort reliever or to aid in or contribute to reducing side effects of the discomfort reliever. The nutritional supplements in Applicant's claimed method are in addition to and do not include any agents in the unit dose of orally consumable material, which are adapted to aid in or contribute to discomfort relieving functions of a discomfort reliever or to aid in or contribute to reducing side effects of the discomfort reliever. So, vitamin C in the pain medicine of Tsunoda is not within the group of nutritional supplements in Applicant's claimed method.

Yeh et al disclose medicine for periodontal disease (see column 1, lines 6-7 and column 2, lines 1-12). Periodontal disease is not a discomfort, and medicine for periodontal disease is not a discomfort reliever. "Discomfort" is defined at page 4 in the above captioned patent application, to refer to discomfort from at least one of: minor aches and pain associated with a common cold, headache, toothache, backache, muscular aches, menstrual cramps, minor pain of arthritis, fever, running nose, sneezing, itching of nose or throat, itchy watering eyes due to hay fever or other upper respiratory allergy, insomnia (difficulty in falling asleep), sleepiness, fatigue and drowsiness. Thus, discomfort as used in the above captioned patent application is limited to the indications specified in its definition. These specified indications do not include periodontal disease of Yeh et al. "Discomfort reliever" as used in the above captioned patent application, is defined at page 4 to refer to predetermined

pharmaceutically ffective amounts of orally consumable material adapted for temporary relief of at least one discomfort. Thus, discomfort reliever, as used in the above captioned patent application, is limited to material adapted for temporary relief of at least one specified indication in the definition of discomfort. These specified indications do not include periodontal disease. So, Yeh et al do not disclose a discomfort, or a discomfort reliever.

Lambelet discloses a pharmaceutical container, as see column 2, lines 15-40. Applicant's claimed method provides supplements for nutrition, an indication of a percent of a recommended daily value (or amount) for each nutritional supplement and discomfort reliever. Lambelet does not disclose supplementing nutrition, a nutritional supplement, indicating a percent of a recommended daily value (or amount) of a nutritional supplement, a discomfort or a discomfort reliever.

Thus, neither SS Pharmaceutical, Tsunoda, Yeh et al nor Lambelet, disclose supplementing nutrition, indicating a percent of a recommended daily value (or amount) of a nutritional supplement, or providing a nutritional supplement, which is not adapted to aid in or contribute to discomfort relieving functions of a discomfort reliever or to aid in or contribute to reducing side effects of the discomfort reliever, as is required by the method claimed by Applicant. Accordingly, claims 26-30, 32-35 and 37-47 are not unpatentable over SS Pharmaceutical in view of Tsunoda, Yeh et al and Lambelet.

YEH ET AL IS NONANALOGOUS ART

Yeh et al fails to qualify as analogous art under the Deminiski criteria of whether the art is in the same field (relieving discomfort, as used in the above captioned patent application, and supplementing nutrition) and reasonably pertinent to the particular problem with which the inventor is involved, (indicating a discomfort reliever, as used in the above captioned patent application and indicating a daily amount of a nutritional supplement), In re Clay 23 USPQ 2d 1058, 1060 (1992, CAFC). Thus, Yeh et al is too remote to be treated as prior art, In re Sovish 769 F2d 738, 741; 226 USPQ 771, 773 (Fed.Cir., 1985). Yeh et al is directed to the field of medication for periodontal disease, see column 1, lines 6-7

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and column 2, lines 1-12. Yeh et al disclose medication for periodontal disease and not for a discomfort or supplementing nutrition as in the method claimed by Applicant. Thus, Yeh et al do not include disclosure in the field or disclosure pertinent to the problem with which Applicant is involved in the above captioned patent application. So, Yeh et al is not pertinent art, as Yeh et al is not part of the art to which the subject matter sought to be patented pertains Sovish. Thus, Yeh et al is too remote to be treated as prior art. Accordingly, the rejection of claims 26-30. 32-35 and 37-47 as obvious over references in combination with Yeh et al is improper.

THE APPLIED REFERENCES DO NOT DISCLOSE THE FEATURES OF THE CLAIMED INVENTION OR ANY BENEFIT FROM THE USE THEREOF

The absence from the applied references of an explicit requirement of the claims makes the rejection improper, In re Evanega 4 USPQ 2nd 1249 (CAFC, 1987). Neither SS Pharmaceutical, Tsunoda, Yeh et al nor Lambelet disclose nutritional supplements which are not adapted to aid in or contribute to discomfort relieving functions of a discomfort reliever or to aid in or contribute to reducing side effects of the discomfort reliever, as claimed by Applicant. This absence from SS Pharmaceutical, Tsunoda, Yeh et al and Lambelet of such nutritional supplements which are explicitly required by claims 26-30, 32-35 and 37-47 makes the rejection improper, In re Evanega.

SUPERIOR RESULTS

The statute does not require a patentable invention to be superior Demaco Corp v F Von Langsdorff Licensing Ltd. 7 USPQ2d 1222 (Fed. Cir 1988). Neither SS Pharmaceutical, Tsunoda, Yeh et al nor Lambelet disclose nutritional supplements which are not adapted to aid in or contribute to discomfort relieving functions of a discomfort reliever or to aid in or contribute to reducing side effects of the discomfort reliever, as in the method claimed by Applicant. Applicant's claimed invention provides superior results to SS Pharmaceutical, Tsunoda, Yeh et al and Lambelet by providing nutritional supplements which are not adapted to aid in or contribute to discomfort relieving functions of a discomfort reliever or to aid in or contribute to reducing side effects of the discomfort reliever. Accordingly, beyond the requirements of the statute, claims 26-30, 32-35 and 37-47 are patentable over SS Pharmaceutical in view of Tsunoda, Yeh et al and Lambelet...

SS PHARMACEUTICAL AND TSUNODA TEACH AWAY FROM THE INVENTION

Nutritional supplements which are not adapted to aid in or contribute to relieving discomfort, are taught away from by disclosure of Vitamin C for discomfort relief in SS Pharmaceutical and Tsunoda. Essentially, teaching away from the invention by the art, is a per se demonstration of prima facie nonobviousness, In Re Dow Chemical Co. 5 USPQ 2d 1529 (CAFC), 1988. SS Pharmaceutical and Tsunoda by teaching away from the claimed invention are per se demonstrations of prima facie nonobviousness of the claimed invention. Accordingly, SS Pharmaceutical and Tsunoda demonstrate the prima facie nonobviousness of claims 26-30, 32-35 and 37-47.

LACK ANY TEACHING FOR THE COMBINATION OF REFEREENCES

A proper combination of references requires a teaching in the references to suggest the combination thereof, <u>In re Sernaker</u> 702 F2d 989, 217 U.S.P.Q. 1 (CAFC, 1983). There is no teaching in SS Pharmaceutical, Tsunoda, Yeh et al and Lambelet to suggest the combination thereof to provide the method of Applicant's invention. Accordingly, the combination of SS Pharmaceutical, Tsunoda, Yeh et al and Lambelet is improper, <u>In re Sernaker</u>.

THE COMBINATION OF REFERENCES IS A HINDSIGHT RECONSTRUCTION OF APPLICANT'S INVENTION

One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention. <u>In re Fine</u>, 837 F2d

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1071, 1075, 5 USPQ 2d 1598, 1600 (Fed. Cir. 1988). It is legal error to use the inventor's patent specification teaching of both a novel and nonobvious invention as though it were prior art in order to make claims appear to be obvious In re Pleuddemann, 901 F2d 823, 828, 15 USPQ 2d 1738, 1742 (Fed. Cir 1990). In constructing the final rejection of Examiner combines SS Pharmaceutical, Tsunoda, Yeh et al and Lambelet without any teaching in the references for the combination thereof. The combination of SS Pharmaceutical, Tsunoda, Yeh et al and Lambelet in the final rejection is legal error.

CONCLUSION

Nutritional supplement as indicated in the method claimed by Applicant is a new (additional) component not disclosed in the prior art of record. All of the limitations of a claim must be considered meaningful. Patentability is supported by the new and unobvious functional relationship between an enclosure and indicating a percent of a recommended daily amount of nutritional supplement (as used in the above captioned patent application) in the unit dose, The claims are patentable over the nonanalogous prior art applied. The claims are patentable as, the prior art applied does not disclose the features or benefits of the claimed invention. The applied references teach away from the invention and lack any teaching for the combination thereof. The applied combination of references is based upon improper hindsight reconstruction of Apellant's invention.

Withdrawal of the Final Rejection and allowance of the claims is respectfully requested.

Respectfully submitted.

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